Testimony of Jonathan Coon,

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before the

Subcommittee on Commerce, Trade and Consumer Protection of the

House Energy & Commerce Committee September 15, 2006

Mr. Chairman and Members of the Subcommittee, my name is Jonathan Coon and I am the CEO of 1-800 CONTACTS. Our company is the largest direct marketer of prescription contact lenses, serving approximately two million consumers.

I appreciate the opportunity to appear before the Subcommittee today. I am grateful to the Subcommittee for investing time on the important issues facing America's 38 million contact lens wearers.

Our company believes that contact lens wearers should be afforded two basic consumer protections:

- 1. Every contact lens wearer holding a valid prescription should have the freedom to choose where her prescription is filled.
- Every contact lens wearer should feel confident that her prescription is based on health needs and not influenced by the prescriber's financial interests.

Unlike most pharmaceuticals, contact lenses are regulated medical products that are sold by the prescriber, creating an inherent conflict of interest. Congress reviewed this conflict in detail in the 2003 hearings held before the passage of

the Fairness to Contact Lens Consumers Act (FCLCA). In the FCLCA report, Congress recognized this conflict of interest when this committee concluded:

"Consumers continue to face a difficult time getting prescriptions filled by alternative third party sellers due to prescription verification obstacles. Unlike medical doctors who are prohibited from selling the drugs they prescribe, eye doctors and optometrists ("doctors") are able to fill the contact lens prescriptions they write. This sets up an inherent conflict of interest because third party sellers are forced to compete for the sale of lenses with the individual who is writing the prescription."

The committee recommended, and Congress agreed, that based on an "unusually high number of consumer complaints in states that rely on active verification schemes" that "a passive verification system ensures that consumers are not caught in the competitive tug-of-war between doctors and third party sellers for the sale of contact lenses."

Congress understood in passing the FCLCA that having a copy of the prescription is meaningless if the retailer chosen by the consumer cannot get the prescription verified. For example, when consumers seek to refill their prescriptions for medicines, it's generally a simple process – the consumer goes to his or her local pharmacy, the pharmacy calls into the prescribing physician and the physician's office then promptly confirms, corrects or rejects the refill. That's the way it should work with refills of contact lens prescriptions – but in most cases it does not.

Since eye care professionals both prescribe and sell contact lenses, verification amounts to the consumer asking their doctor's permission to buy lenses from a competitor. Before the FCLCA, these verification requests were ignored more than half the time. After the FCLCA, these verification requests are still ignored more than half the time, but this lack of response does not prevent the consumer from buying from the doctor's competitor. Several states examined this issue

closely and some enacted different verification systems before Congress enacting the FCLCA and created a federal standard. The state laws at the time fell into basically two different verification systems.

- 1. "Positive verification" requires a competing seller to wait indefinitely for the eye doctor, who sells contacts, to respond to the verification request. The seller must wait until a response is received and the patient has no recourse other than to complain when the doctor refuses to grant permission to a competitor to make a sale. This method has proven to result in a very large number of consumer complaints.
- 2. "Presumed verification" defines how long an eye doctor has to respond to a verification request when a consumer chooses to purchase from a seller that is not an eye doctor and prevents a doctor from blocking access to competitors by simply ignoring the request. This system requires a seller to verify the prescription directly with the prescriber and gives the prescriber a reasonable time period in which to reply. If the prescriber tells the seller within that time period that the prescription is expired or invalid, the seller must cancel the order. If the prescriber does not respond to the seller within the defined time period, the seller can assume the prescription information is correct and fill the order.

Presumed verification was described by the FTC at the 2003 hearing as a self enforcing system because doctors have a financial interest to enforce the law and prevent invalid prescriptions from being filled by competitors. However, unlike a positive verification system in which the doctor's refusal to respond can stop a patient's order from a third party, a presumed verification system requires the doctor to actively do something to cancel the patient's order.

A positive, or active verification system can work where the prescriber has no conflict of interest and does not compete with others filling the prescription. The

verification process, communication methods, and time frame for response between medical doctors and pharmacies are not defined. This system works despite the lack of defined rules because medical doctors do not sell drugs and pharmacies do not prescribe. The <u>roles</u> of medical doctors and pharmacies are defined and limited in such a way that cooperation is not a problem. Pharmacies are not asking a competitor for permission to fill an order. Medical doctors are not losing income by cooperating with pharmacies.

Where positive verification systems have been implemented for the sale of replacement contact lenses, the result has been widespread consumer dissatisfaction. Thousands of consumers waited so long for a verification response that more than half ultimately canceled their orders. Most of these customers give up and went back to the doctor to purchase lenses. Many just kept wearing their old lenses.

In just Texas alone, where an indefinite time period system had been in place for more than a year, our company canceled more than 40,000 customer orders solely for non-response by the eye doctor. Consumers filed more than 4,300 hand-signed complaints with the optometry board. Additional complaints were filed by consumer groups. The optometry board (made up of optometrists) took no action on any of the consumer complaints. The result was an unmitigated disaster for Texas consumers with more than half of all third party seller orders canceled simply because the eye doctor never responded - in any time period.

A presumed verification system was first called for by the Federal Trade Commission ("FTC") staff in its comments before the Connecticut Opticians Board in 2002. FTC proposed that the right way to deal with the conflict of interest of doctors selling what they prescribe and the competitive relationship between eye doctors and third party sellers was a presumed or passive verification system. The FTC stated that the right verification system for this market was one in which "a valid prescription, communicated to the seller by the

patient, can be presumed verified if the doctor is contacted and given sufficient opportunity to correct any errors."

This compromise system was enacted into law in California in 2002. The system was developed with the involvement of ophthalmologists, optometrists, consumer groups, the California Medical Board, and the California Optometric Association. In their written statement supporting the California bill, the California Optometric Association concluded that the law "supports safe and responsible patient access to contact lens prescriptions" and "strikes a reasonable balance between access and accountability." Our Company processed more than several hundred thousand orders under this system before the FCLCA was enacted and did so without any complaints being received by the medical board from consumers, online sellers, or eye doctors.

Based on the above mentioned testimony, evidence and hearings, the FCLCA was enacted and the passive verification system has been the law of the land since December of 2003. To date there has been no meaningful evidence that the law is not working or that passive verification is not the right system to manage the conflict of interest of a doctor selling what they prescribe. Although some on today's panel will probably make unsubstantiated claims to the contrary, Congress did not make a mistake in adopting a passive verification system as there is no evidence to support their assertion that this provision of the law should be repealed and replaced with the already tested and failed positive verification system. Instead, the verification system under the FCLCA has allowed millions of consumers the right to purchase their contact lenses at the retailer of their choice. However, a loophole to the FCLCA has surfaced which threatens to erase all the freedoms Congress gave to consumers as part of the Act.

Unlike pharmaceuticals, contact lens prescriptions are brand specific – with no generic lenses and no substitution allowed.

Once prescribed a specific lens, federal law only allows the patient to be sold the "same contact lens . . . manufactured by the same company" (15 U.S.C. 7603(f)). Unlike pharmaceuticals, the prescriber can specify a lens sold only to doctors and effectively force the patient to purchase lenses at the doctor's store or through an affiliated retailer. Trade advertisements promise these benefits to doctors who prescribe restricted lenses.

To provide patients with basic consumer protections, the FCLCA seeks to provide consumers with the right to purchase from any retailer, including those not affiliated with a prescribing doctor. The Committee report accompanying the FCLCA states that the law "allows consumers to purchase contact lenses from the provider of their choice."

The FCLCA has had many positive impacts on the marketplace, and has provided many consumers with real benefit. Despite the law's fundamental goals, patients prescribed so-called "doctors only" lenses continue to be locked into buying lenses from the prescribing doctor or a doctor-affiliated retailer. This loophole allows a doctor to comply with the FCLCA by releasing the prescription, but avoid the intent of the law by prescribing a lens that is only available from a doctor or an affiliated retailer.

Mr. Chairman, millions of Americans who wear contact lenses have no more right to choose where they buy lenses today than before the FCLCA was passed. We agree with the Committee's report which states that, "The consumer's right to a copy of their contact lens prescription means nothing unless consumers can fill that prescription at the business of their choice."

"Doctors only" lenses are marketed to eye doctors on their ability to increase prescriber profits by limiting competition and compelling patients to return to prescribers for lens purchases. A brochure for Extreme H2O lenses promises doctors "a lens that cannot be shopped around" and "a lens that will retain your replacement business."

An ad for ProClear lenses entices the doctor with its headline, "Let's see. You'll make more money." The ad goes on to explain to the doctor that "since ProClear Compatibles are only available through your practice, you'll get what you're looking for: Increased patient loyalty and greater profitability."

This is the same scheme that 32 state attorneys general sought to stop in bringing multi-district litigation (MDL 1030) in 1997. At the time, 100 percent of the market was "doctors only," with all three major manufacturers maintaining a "doctors only" distribution policy. The lawsuit led to consent decrees with the then three largest manufacturers – Johnson & Johnson, CIBA Vision, and Bausch and Lomb – requiring them to abandon their "doctors only" policies and sell to non-prescribers on the same terms as prescribers.

H.R. 5762, introduced by Congressman Lee Terry, is necessary to assure that all consumers are afforded the protections of these consent decrees and those promised by the FCLCA. The bill codifies the consent decrees, under which 80 percent of all contact lenses have been successfully and efficiently sold since 2001.

Like the consent decrees it seeks to codify, H.R. 5762 would protect consumers and promote competition and would remove the ability of any manufacturer to entice doctors to with offers of increased profits by restricting consumer choice.

Thirty-nine state attorneys general said it best in endorsing the legislation:

"We are very concerned that, unless all manufacturers abandon these restrictive distribution policies, the effect will be to harm consumers. Consumers will pay higher prices to purchase replacement lenses and may suffer adverse health consequences if the higher prices cause them to replace their lenses less frequently than recommended. Because of these risks, the restrictive distribution policies are undermining both the FCLCA and the MDL 1030 settlements."

Despite the fact that manufacturers market "doctors only" lenses on their utility in restricting competition and locking in consumers, a February 2005 FTC report concluded that the marketing practice does not appear to harm competition and consumers. The FTC study is flawed and best characterized as a snapshot in time of a contact lens market that no longer exists. The reason the FTC study found competition for most lenses is because 32 states sued to stop the three largest manufacturers (at the time) from colluding with eye doctors. H.R. 5762 seeks to codify these settlements before they expire in November of this year. The settlements have worked and have created a competitive market for the lenses made by the companies that are subject to it.

The fundamental flaw in the FTC report is its failure to adequately account for the two defining characteristics of the contact lens market – contact lenses are prescription devices and that eye doctors sell the lenses they prescribe.

We do not dispute the FTC economist's view that a manufacturer offering a retailer increased profits or exclusivity to promote the manufacturer's over-the-counter products is a sound and reasonable marketing strategy for the manufacturer. However, 39 state attorneys general do see a problem for consumers when manufacturers offer doctors increased profits to promote and prescribe a prescription product.

The FTC's analysis ignores the fact that Federal law requires that a contact lens prescription is brand specific and must be filled with the same lens made by the same company as that specified by the doctor. Once a patient pays to be fitted and receives a prescription, if the lens is not available from her chosen retailer, there is no opportunity for the patient to choose another lens made by another manufacturer without paying for another exam and contact lens fitting.

The FTC report is based on the assumption that Internet sellers denied direct access by the manufacture to "doctors only" lenses could obtain these lenses on the so-called "grey" market. Since the report was issued, the "grey" market for

"doctors only" lenses has dried up. Every week, our company turns away thousands of consumers with valid prescriptions because we are not able to obtain the "doctors only" lenses prescribed by their doctor.

It is important to note that CooperVision assures doctors that its lenses are not available from non-prescribing retailers while at the same time assuring the FTC and Congress that its lenses are widely available from non-prescriber affiliated retailers.

CooperVision suggests that H.R. 5762 will adversely affect patient safety by requiring manufacturers to sell "doctors only" lenses to retailers not affiliated with eye doctors. The American Optometric Association (AOA) repeatedly made this same unsubstantiated claim in the multi-district lawsuit – in which it was a defendant. This argument was shown to be without merit. In fact, the AOA's settlement, Section 2(h) reads:

"The AOA shall not represent directly or indirectly that the incidence or likelihood of eye health problems arising from the use of replacement disposable contact lenses is affected by or causally related to the channel of trade from which the buyer obtains such lenses."

In addition, the coordinated effort between CooperVision and the AOA appears to run afoul of the AOA's settlement, which clearly states in Section 2(e):

"The AOA will resist any invitation by any contact lens manufacturer to enlist the AOA's aid in enforcing any manufacturer's distribution policy refusing to sell contact lenses to any channels of trade."

CooperVision's president, Greg Fryling, is quoted in his company's hometown newspaper, *The Rochester Democrat and Chronicle*, July 25th, 2006:

"What we are also trying to do is push this more to optometrists and the American Optometric Association and have them present the case," Fryling said. "In our view, it's as much their battle as it is our battle."

It is odd for a manufacturer to publicly invite doctors to defend the manufacturer's restrictive distribution policy. The AOA appears to agree, and sent a letter to CooperVision (attached) regarding "an immediate concern of the American Optometric Association" – namely, "marketing materials for contact lenses that emphasize factors subordinate to what is clinically best for the health of the patient's eyes and vision" and asking CooperVision to "review your company's marketing and advertising policies." Even the AOA recognizes that it cannot openly support CooperVision's offer of financial incentives to doctors to promote and prescribe CooperVision lenses.

Medical doctors know that exclusive distribution deals between doctors and manufacturers are wrong. The American Medical Association code of ethics, 8.063, section 4 states:

"Physicians should not participate in exclusive distributorship of healthrelated products which are available only through physician's offices. Physicians should encourage manufacturers to make products of established benefit more widely accessible to patients than exclusive distribution mechanisms will allow."

Despite their settlement with 32 states and the AMA code, the AOA is opposing a bill that would eliminate exclusive distributorships between eye doctors and manufacturers and protect consumer choice.

The AOA stated in a January 31, 2006 letter that "the AOA strongly endorses the idea that patients should be able to purchase their contact lenses from whomever they wish." And yet the AOA "strongly opposes" a bill which would protect the patient's right to do so. The bill does not limit what a doctor can prescribe for any patient. The bill does not limit the doctor's ability to sell any lens to any patient.

The AOA cannot have it both ways. If they oppose a bill that has no affect on doctors and protects patient choice, then they oppose patient choice.

We ask the Committee to reaffirm the intent of the Fairness to Contact Lens Consumers Act - to allow consumers to fill their prescriptions for contacts where they choose. Thirty nine state attorneys general have signed a letter expressing the urgent need for this legislation in order to ensure the consumer protection intended by the FCLCA and the 32 state settlements (MDL 1030). Please pass HR 5762 and close this loophole before the settlements expire November 1st.

Mr. Chairman, thank you for the opportunity to testify. I would be pleased to answer any questions you may have.